

ER/DL SPL Team Meeting

Minutes

August 18, 2010

Chair of today's meeting: Michelle Halliez

Topics discussed

1. Establishment validation issues - Jackie Mohns
 - Cause of problem: CM not electronically registered and business operations not aligned between DER and DL
 - Many files are being rejected because they don't pass validation.
 - FDA is putting burden on the drug listing company to work with the CM to correct.
 - What is best approach for now???
 - Are sponsors worried about listing incorrectly? Yes.
 - Should sponsors leave CMs off? No. Data would not be accurate.
 - Can validation rules be turned off? DRLS / FDA response: No (see 7/21 meeting minutes of discussion with Paul Loebach).
 - Lonnie has said that he is not getting too many questions, and he has offered to manually override.
 - Recommendations:
 - Send questions and issues to Lonnie -- so that he knows the extent of the errors/problems that sponsors are tweaking.
 - Also send him information about the nature of number of problems.
2. Update on Drug Listing meeting with Paul Loebach
 - Minutes completed and distributed.
 - Hopefully Paul will be willing to meet with us again to discuss other questions
 - Pat to create space on wiki to collect questions for future discussions.
3. New section title: "instructions for use." How is this supposed to be used?
 - Pat asked Lonnie about this and received a very brief response.
 - This may relate to new SPL directives that are not yet final.
 - Pat will create a new space on the wiki to collect SPL related questions.

Outstanding follow-up items

- Process for export products (Pat/Jean)
- Rationale for why it is difficult to have R3s removed manually from Daily Med (Howard/Jean/Pat)
- Communicating with FDA about validation errors – that result in issues with import, not being able to be compliant with instructions in approval letters, etc. (Warren, Jean, Dragan, and Jessica)
- Create space on wiki to collect questions for future discussions with FDA: DRLS and SPL. (Pat)